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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,581	10/23/2001	John H. Stevens	HRT-287	4692

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EXAMINER

ISABELLA, DAVID J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/19/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,581

Applicant(s)

STEVENS, JOHN H.

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-37 is/are pending in the application.
- 4a) Of the above claim(s) 32-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 15-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/03</u> . | 6) <input type="checkbox"/> Other: ____ |

Status of the Claims

Claims 7,8 have been cancelled and replaced with newly added claims 15-37.
Claims 1-6,9-14 remain withdrawn from consideration as being directed to non-elected invention/species.

Election/Restrictions

Newly submitted claims 32-37 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original scope of the elected invention is directed to a valve and the newly added claims 32-37 are directed to a valve device which includes the combination of a catheter and guidewire. Note, the scope of the valve of claims 32-37 is not commensurate with the scope of the valve of claims 15-31.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-37 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-20,30 are rejected under 35 U.S.C. 102(b) as being anticipated by Peale (15192).

Peale discloses a valve for implantation comprising a flexible sleeve and at least one cups configured to permit blood flow through in a single direction. The limitation of “the valve being capable of insertion to the desired location via a catheter” fails to particularly set forth features that enable the valve capable of being inserted by a catheter. Based on the structure set forth, it appears that the obvious parameters that allow for the valve to be inserted via catheter may be directed to flexibility and size. According to Peale, the check valve is constructed to imitate the valves of the arterial and other portions of the human organization. The valve and the sleeve are intended to be flexible. Clearly, in so far as meeting the positive recitation of the claimed features, Peale discloses and meets these limitations. There is no structural element of the valve of Peale that would preclude its being inserted via a catheter.

Claim 30, see lines 70+ of Peale.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-29, are rejected under 35 U.S.C. 103(a) as being unpatentable over Peale as applied to claim 15 above, and further in view of Sakura, Jr (4214587)

Sakura, Jr teaches a anastomosis device comprising a cylindrical radially resilient spring formed with outwardly extending fastening elements for attaching a vessel to a natural conduit. The device of Peale may be inserted into the natural conduit but must rely on strict adherence to sizing diameters to match the diameter of the natural conduit. Sakura, Jr allows for direct attachment of the valve of Peale to the natural conduit without strict adherence to matching diameters thus alleviating the need for frictional fit. Moreover the spring of Sakura, Jr allows the attaching vessel to pulsate in a fashion similar to that of the natural conduit. It would have been obvious to one with ordinary skill in the art to attach the vessel of Peale to the natural conduit via a compressible spring member as shown by Sakura, Jr. With respect to claim 29, clearly the spring is capable of being balloon expandable as broadly claimed.

Claim Rejections - 35 USC § 103

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peale as applied to claim 15 above, and further in view of Navia et al (5156621).

Peale check valve was patented back in 1856 well before the use of natural tissues in valve replacement. Navia, et al teaches that it was known in 1988 to use natural tissue in forming a valve for replacing an existing valve. To replace the synthetic material of Peale with natural tissues to ensure better invivo characteristics and tribiologic response would have been obvious from the teachings of Navia, et al.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DAVID J ISABELLA** whose telephone number is 703-308-3060. The examiner can normally be reached on **MONDAY-FRIDAY**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **CORRINE MCDERMOTT** can be reached on 703-308-2111. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)..


DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
MARCH 9, 2004